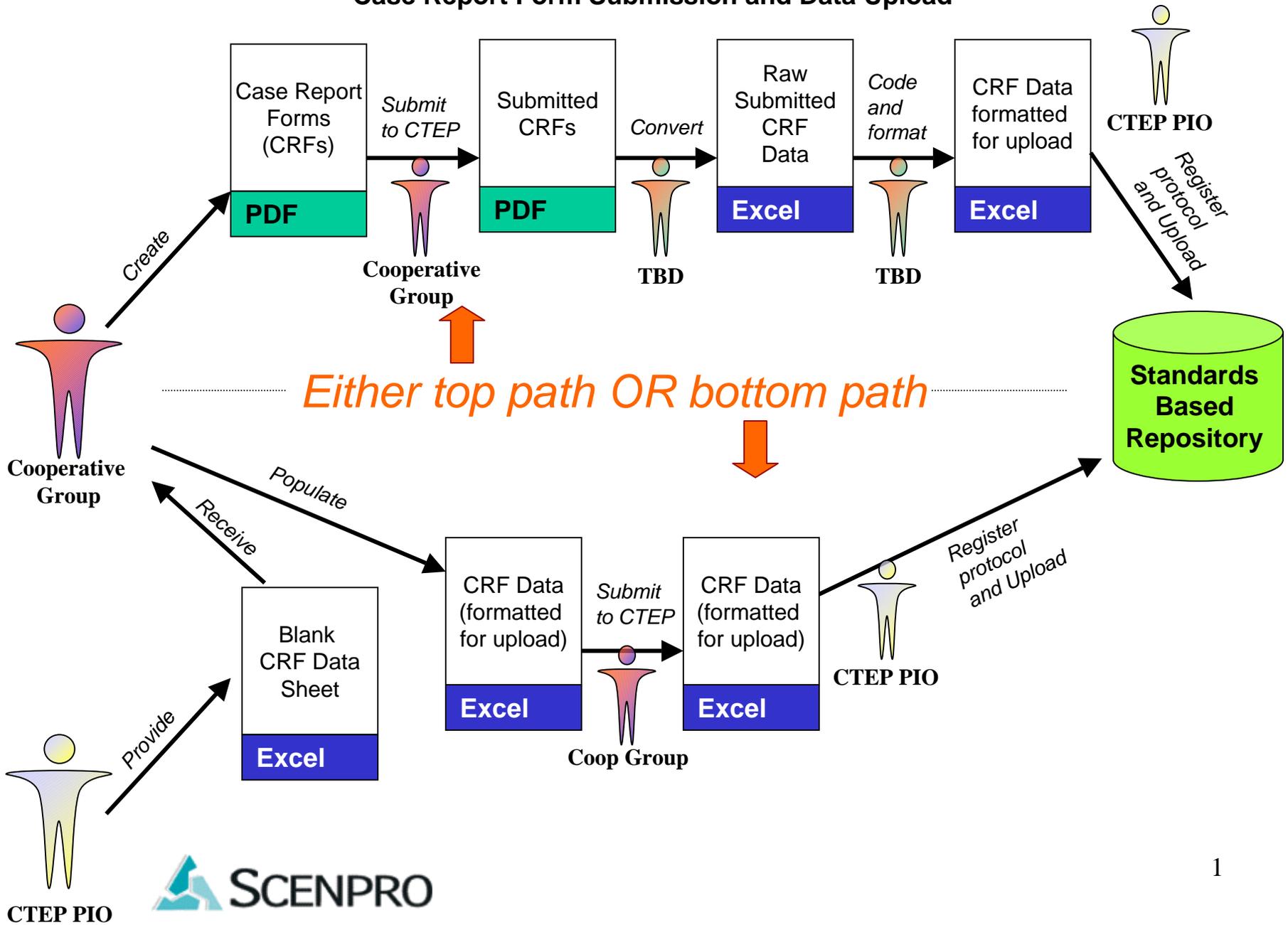


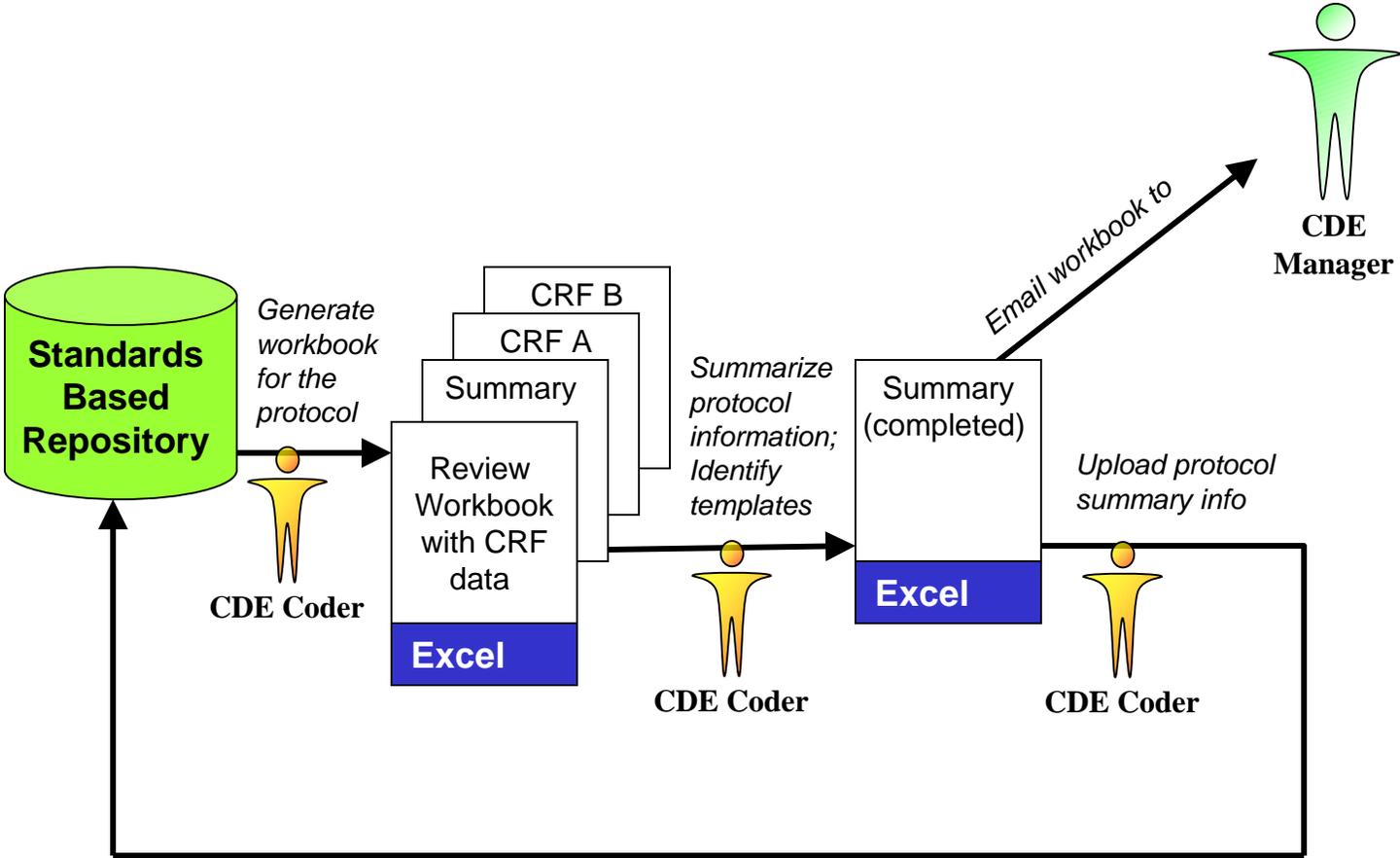
CDE Compliance Review Tools Workflow – To Be

Case Report Form Submission and Data Upload



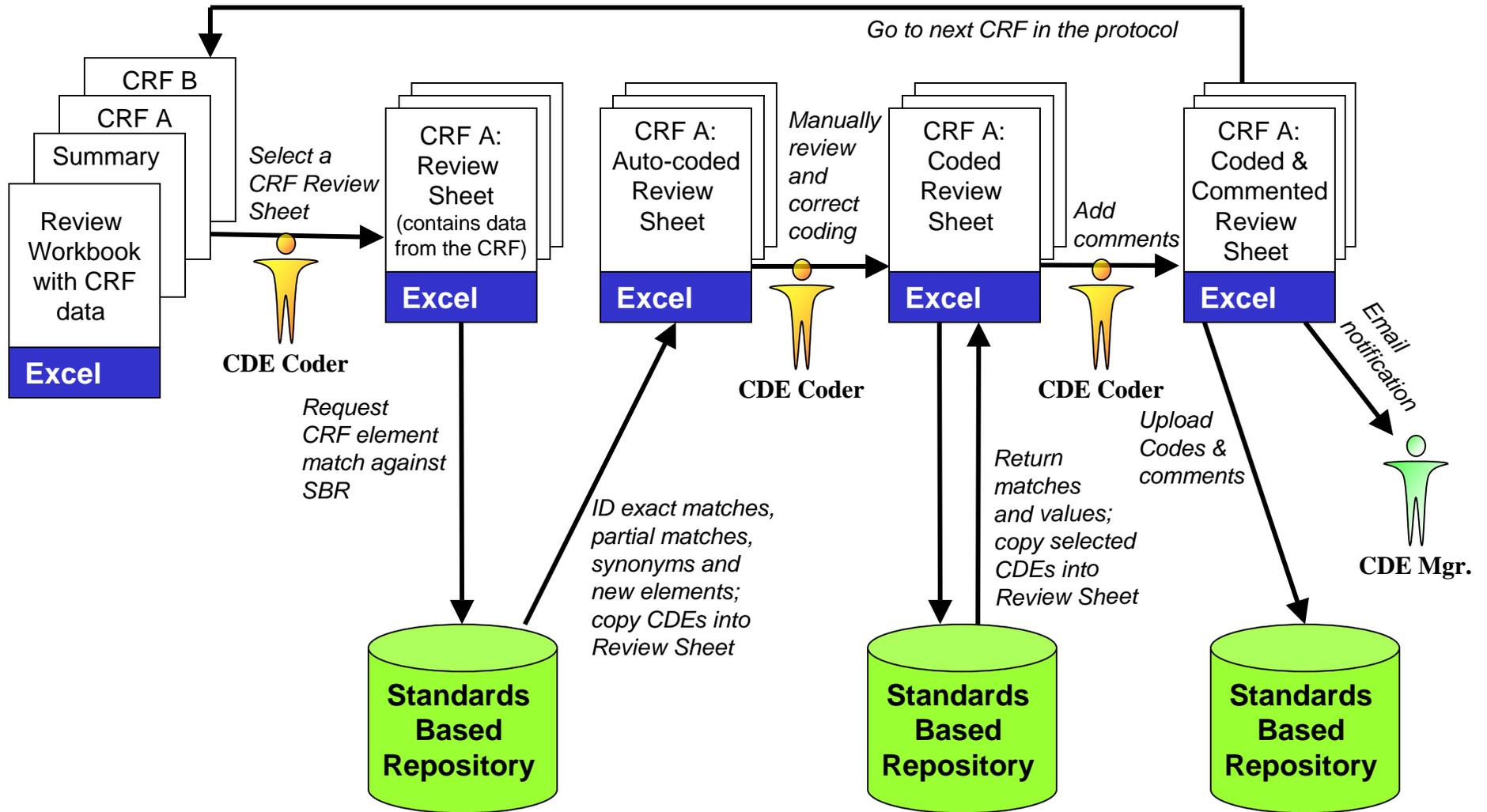
CDE Compliance Review Tools Workflow – To Be

Set Up Review Workbook



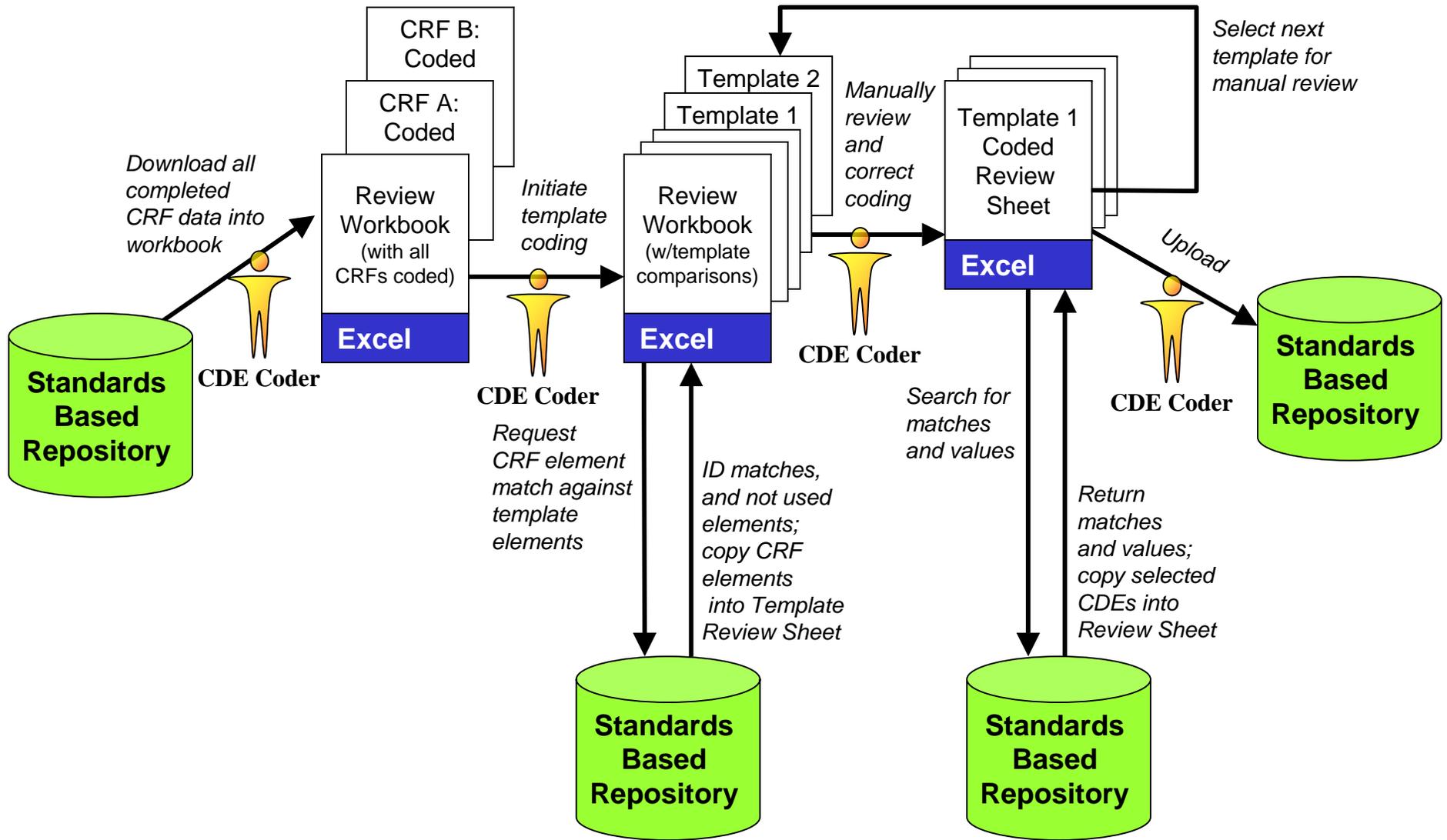
CDE Compliance Review Tools Workflow – To Be

Code CRF for CDE Compliance



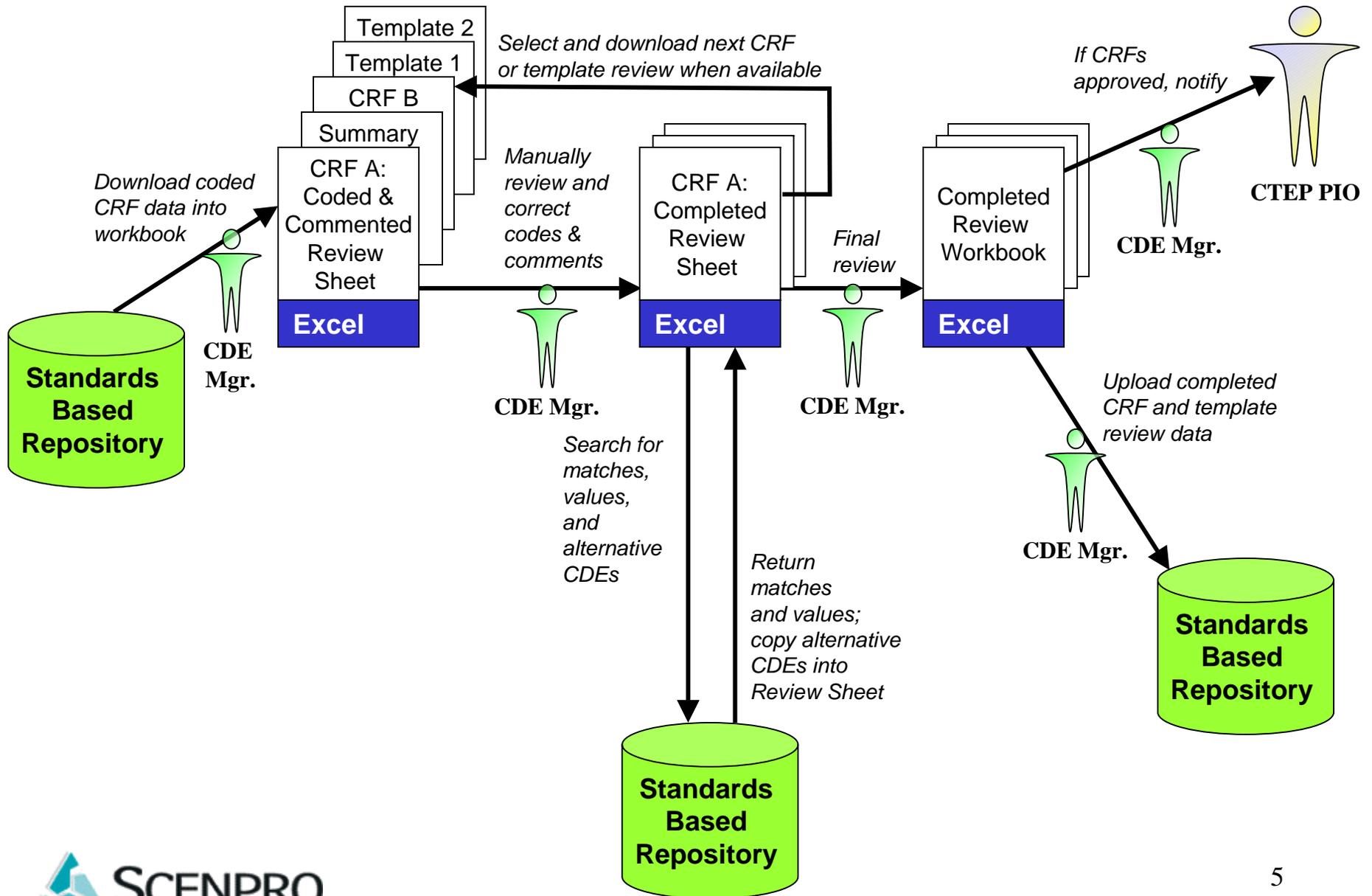
CDE Compliance Review Tools Workflow – To Be

Evaluate Templates Against All CRFs in Protocol



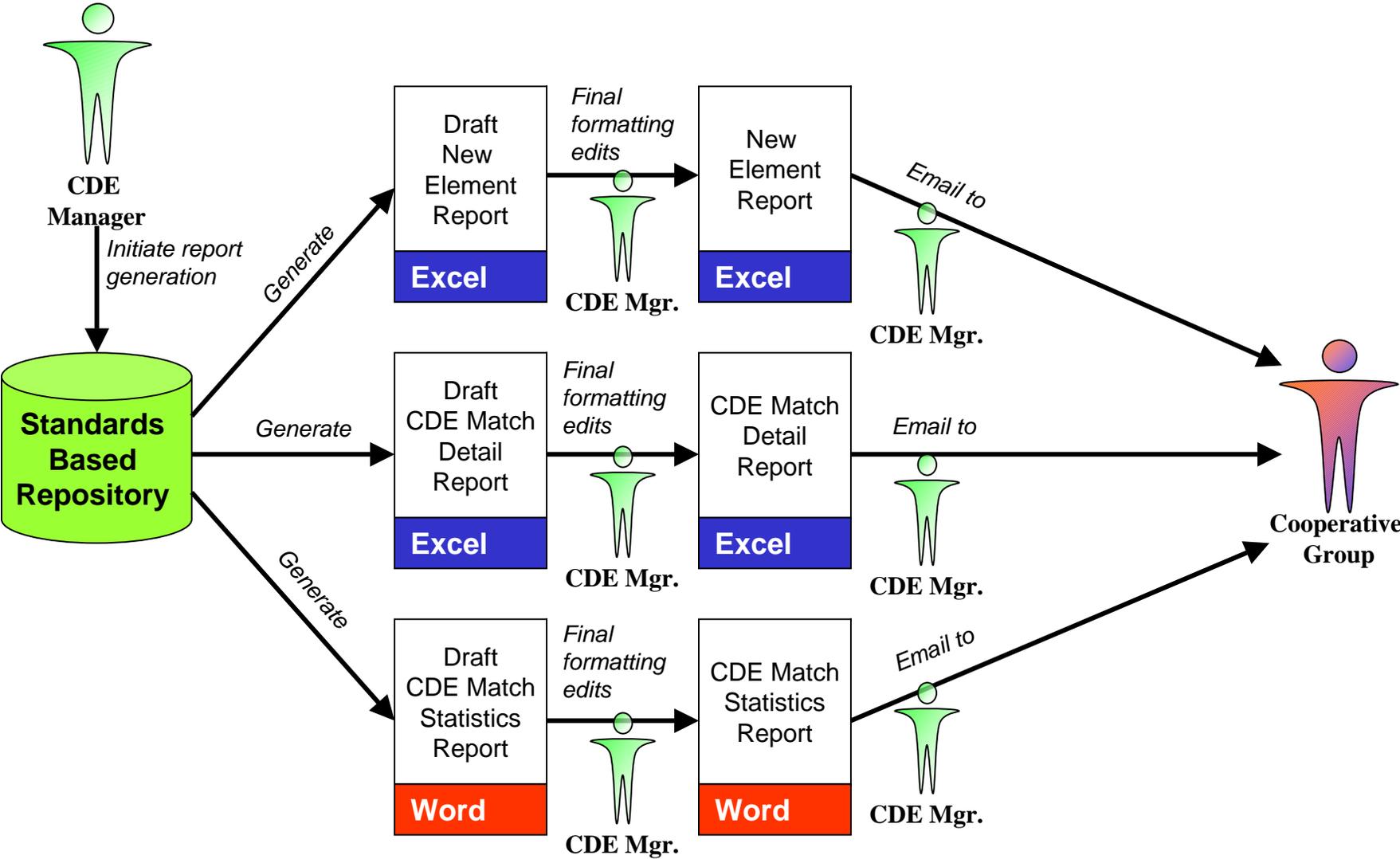
CDE Compliance Review Tools Workflow – To Be

Complete CRF Coding for CDE Compliance



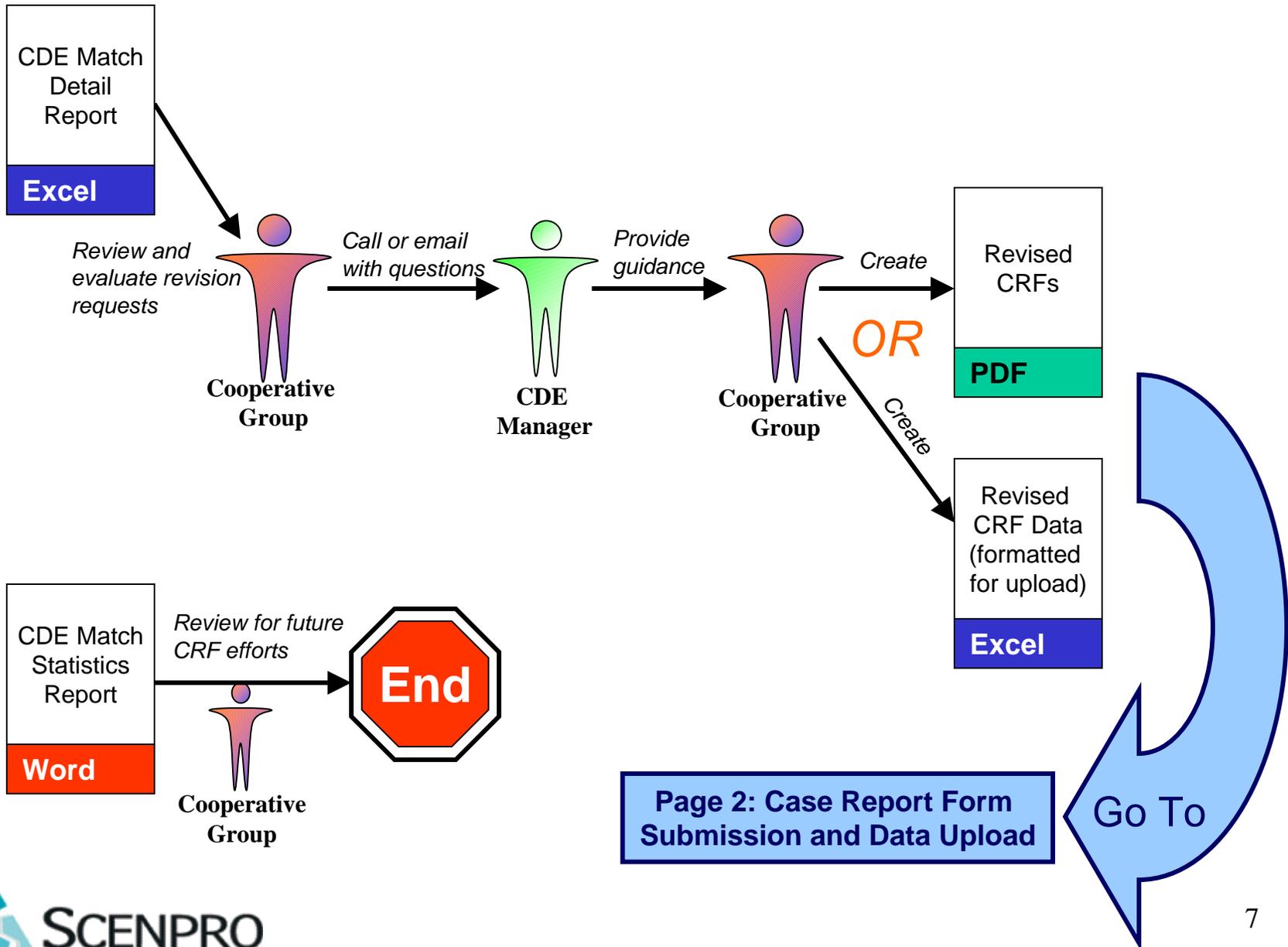
CDE Compliance Review Tools Workflow – To Be

Generate and Distribute Reports



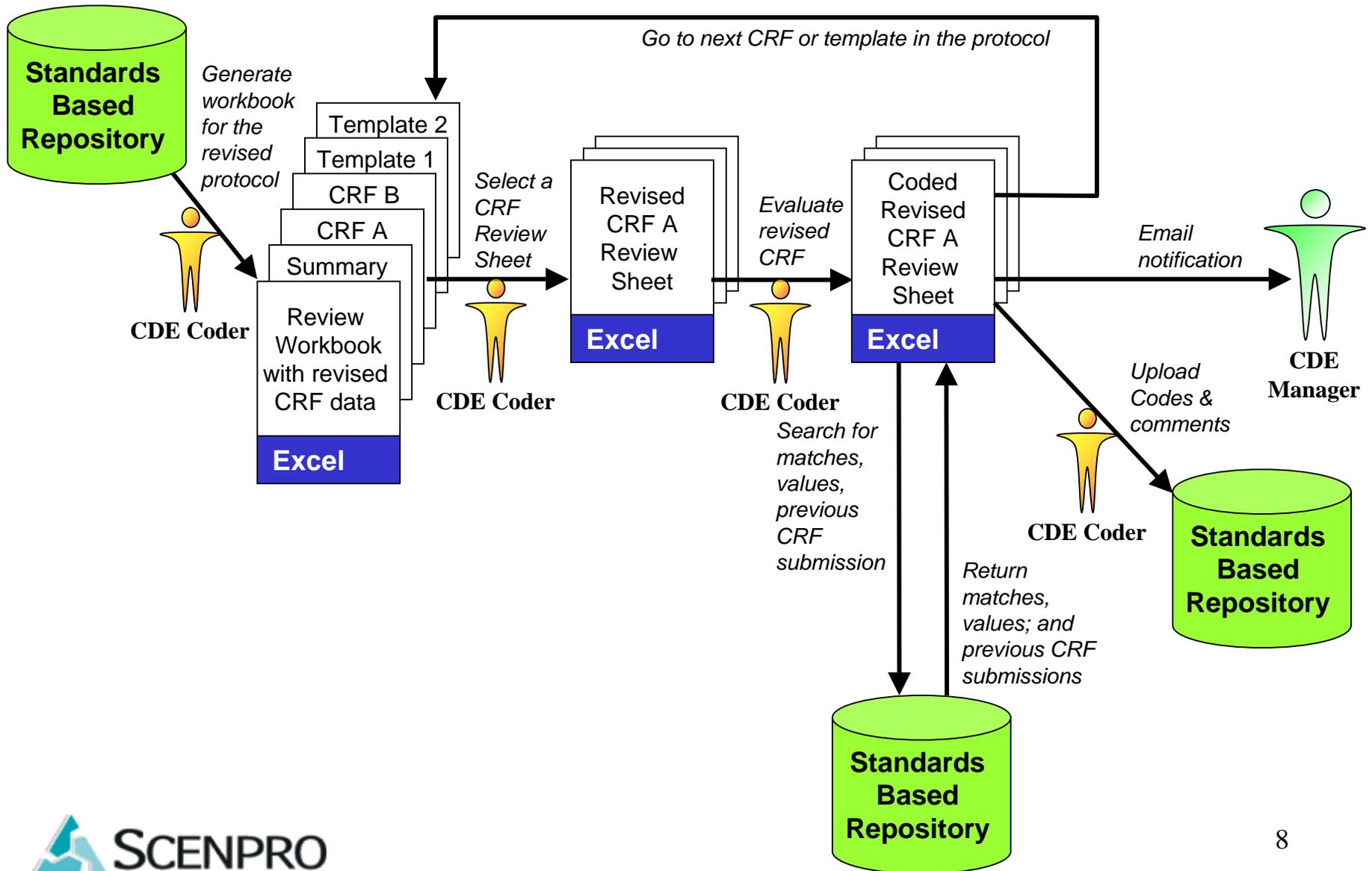
CDE Compliance Review Tools Workflow – To Be

Revise Case Report Forms



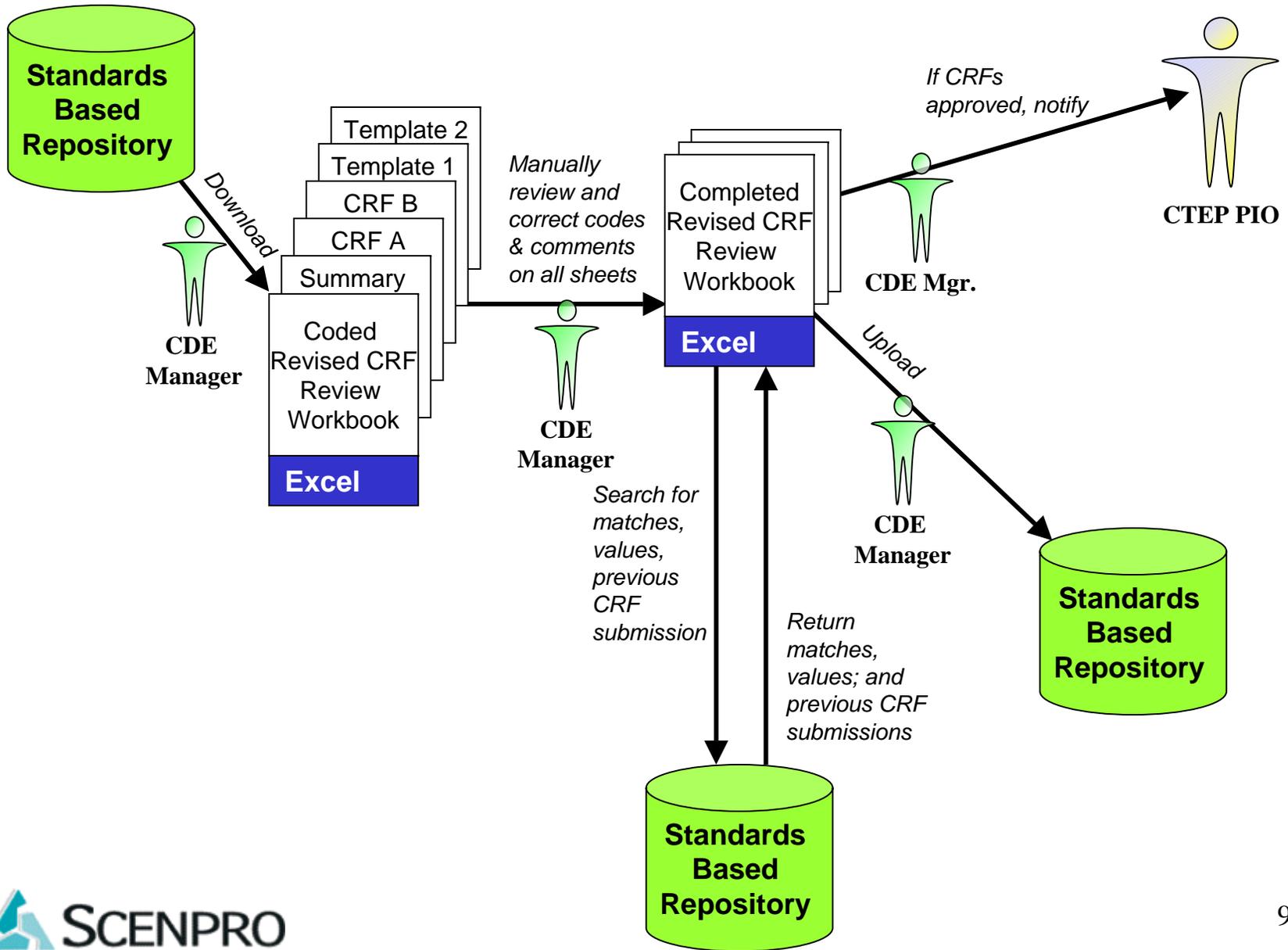
CDE Compliance Review Tools Workflow – To Be

Code Revised CRFs for CDE Compliance



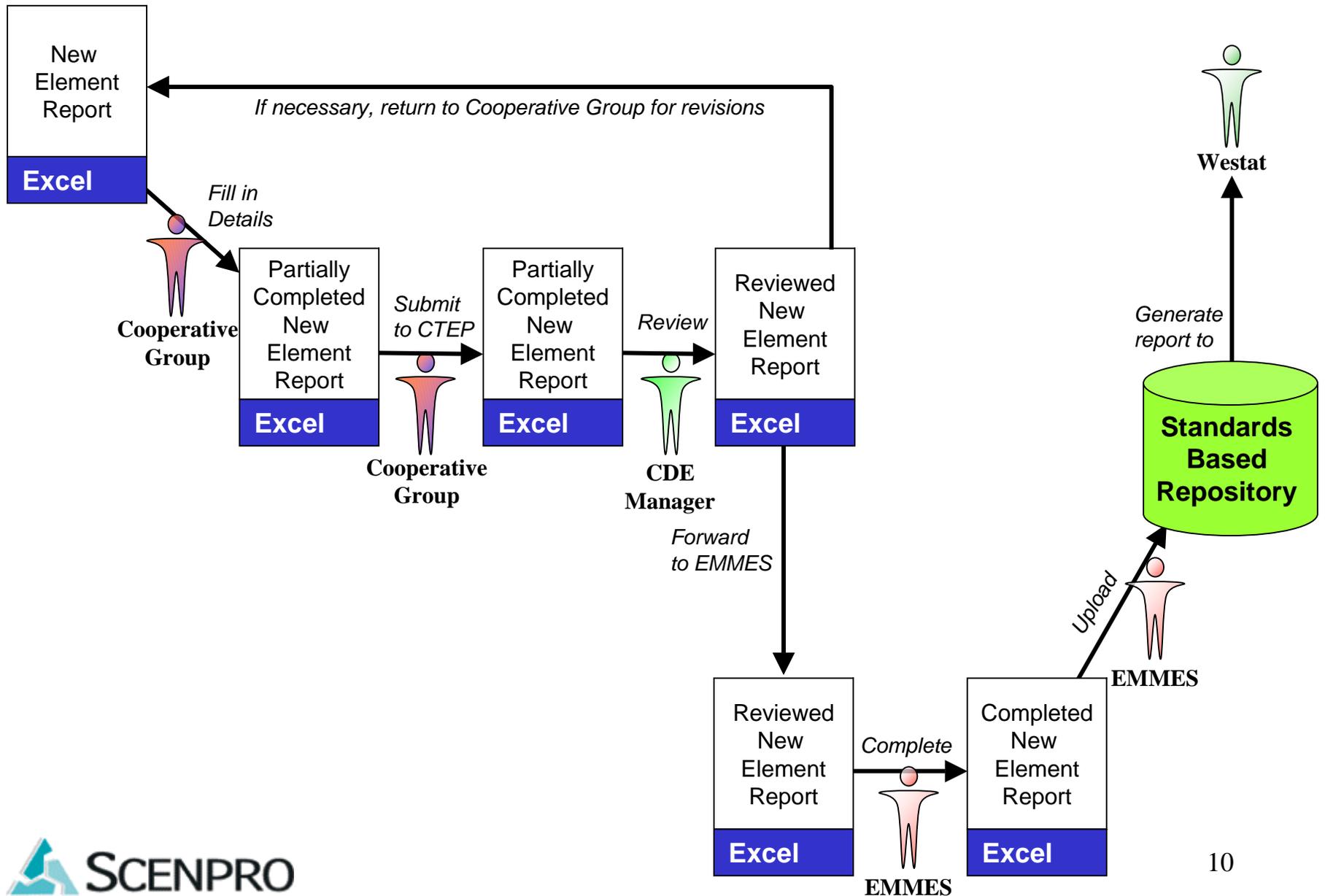
CDE Compliance Review Tools Workflow – To Be

Approve Revised CRFs for CDE Compliance



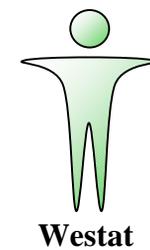
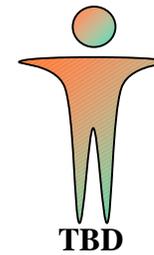
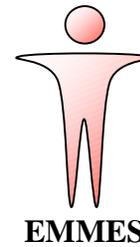
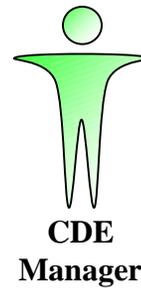
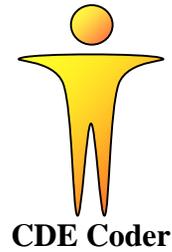
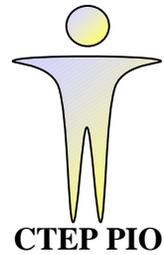
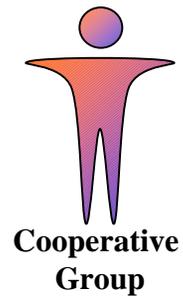
CDE Compliance Review Tools Workflow – To Be

Define New Data Elements



CDE Compliance Review Tools Workflow – To Be

Process Participants



CDE Compliance Review Tools Workflow – To Be

Documents and Document States – Part 1

Document

Document States

Case Report Form

Case Report Forms (CRFs)	Submitted CRFs	Revised CRFs
PDF	PDF	PDF

Submitted CRF Data

Raw Submitted CRF Data	CRF Data formatted for upload	Blank CRF Data Sheet	Revised CRF Data (formatted for upload)
Excel	Excel	Excel	Excel

Protocol CRF Summary

Summary (blank)	Summary (completed)
Excel	Excel

CRF Review Sheet

CRF Review Sheet (contains data from the CRF)	CRF Auto-coded Review Sheet	CRF Coded Review Sheet	CRF Coded & Commented Review Sheet	CRF Completed Review Sheet
Excel	Excel	Excel	Excel	Excel

CDE Compliance Review Tools Workflow – To Be

Documents and Document States – Part 2

Document

Document States

Template Review Sheet

Template Review Sheet (w/template Items only)	Template Coded Review Sheet	Template Completed Review Sheet
Excel	Excel	Excel

New Element Report

Draft New Element Report	New Element Report	Partially Completed New Element Report	Reviewed New Element Report	Completed New Element Report
Excel	Excel	Excel	Excel	Excel

Match Detail Report

Draft CDE Match Detail Report	CDE Match Detail Report
Excel	Excel

Match Statistics Report

Draft CDE Match Statistics Report	CDE Match Statistics Report
Word	Word

CDE Compliance Review Tools Workflow – To Be

Documents and Document States – Part 3

Document

Document States

**Revised
CRF Review
Sheet**

Revised
CRF
Review
Sheet
Excel

Coded
Revised
CRF
Review
Sheet
Excel

Completed
Revised
CRF
Review
Excel